

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Determining the effects of using 1.2% Atorvastatin gel with absorbable membrane on clinical and histological parameters in socket preservation

Protocol summary

Study aim

This study aimed to assess the effect of Atorvastatin gel on clinical and histological parameters in dental socket preservation

Design

Randomized clinical trial with control group, parallel group and double blind, on 15 patients

Settings and conduct

The present clinical trial is performed on 15 patients who need to extract at least two teeth. In each patient, Atorvastatin gel with collagen membranes are used to maintain the alveolar socket on one side and collagen membranes on the other side. The patient is not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Patients who required extraction of two teeth

Intervention groups

Atorvastatin gel with resorbable collagen membrane in intervention group and resorbable collagen membrane in control group

Main outcome variables

Width and height of dental socket; width and thickness of gingiva before and 2 months after intervention; histology index of ossification percentage and thickness of trabeculae, 2 months after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110109005570N11**

Registration date: **2021-07-22, 1400/04/31**

Registration timing: **prospective**

Last update: **2021-07-22, 1400/04/31**

Update count: **0**

Registration date

2021-07-22, 1400/04/31

Registrant information

Name

Parichehr Behfarnia

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effects of using 1.2% Atorvastatin gel with absorbable membrane on clinical and histological parameters in socket preservation

Public title

Effect of Atorvastatin gel on clinical and histological parameters in socket preservation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with healthy systemic condition Single-rooted or

double-rooted teeth Presence of sound buccal and lingual plates after tooth extraction Presence of a minimum of 10 mm vertical bone height without invading the adjacent critical structures,

Exclusion criteria:

Allergy to collagen membrane Severe untreated periodontitis Acute infection or pus at the extraction site

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **2**

15 patients who required extraction of two teeth

Randomization (investigator's opinion)

Randomized

Randomization description

In each patient, one dental socket is selected as the case and the other socket as the control. Randomization method for selecting the socket in each patient is done by the sealed envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant is not able to identify the type of treatment performed. The person performing the histological examination is not aware of the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib- Isfahan University of Medical Sciences

City

Esfahan

Province

Isfahan

Postal code

814673461

Approval date

2020-05-31, 1399/03/11

Ethics committee reference number

IR.MUI.MED.REC.1398.107

Health conditions studied

1

Description of health condition studied

socket preservation

ICD-10 code

K08.40

ICD-10 code description

Partial loss of teeth, unspecified cause

Primary outcomes

1

Description

Length of socket

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Periodontal probe

2

Description

Width of socket

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Periodontal probe

3

Description

Width of keratinized gingiva

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Periodontal probe

4

Description

Thickness of gingiva

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Periodontal probe

5

Description

Percent of ossification of alveolar socket

Timepoint

2 months after the intervention

Method of measurement

Histological evaluation

6

Description

Thickness of new trabecula

Timepoint

2 months after the intervention

Method of measurement

Histological evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: extraction of tooth and placing atorvastatin gel in socket and covering it with claprotect membranes made by Bottis company and then suturing on it

Category

Treatment - Other

2

Description

Control group: extraction of tooth and covering socket by claprotect membranes made by Bottis company and then suturing on it

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental school, Medical University of Isfahan

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Parichehr Behfarnia

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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assistant professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after unidentifying individuals

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

for all researcher

Under which criteria data/document could be used

For a comparative study

From where data/document is obtainable

Dr. Negin Hosseini, assistant professor of dental school,
Shiraz University of Medical Sciences

What processes are involved for a request to access data/document

Request via email to the corresponded and will be send
within 3 months after review

Comments